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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

San Francisco District
1431 Harbor Bay Parkway
Alameda, California 94502-7070
Telephone 510-337-6700

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Our Reference: 29-53428

June 30, 1997

Gary Davis, President
Natural Environmental Solutions
5012 South Arville Street, Suite 10
Las Vegas, Nevada 89118

WARNING LETTER

Dear Mr. Davis:

This letter is written in reference to your marketing and distribution of [redacted] intended for inter-mammary and topical administration for dairy cows. An inspection of your firm on May 20, 1997 by Food and Drug Administration (FDA) Investigator Luis Chavarria has revealed serious violations of the Federal Food, Drug, and Cosmetic Act (Act). Because the labeling and/or promotional materials for the colloidal silver solution you distribute states or suggests that it is intended for the cure, mitigation, treatment, or prevention of diseases in dairy cows, or affects the structure or function of the body, this product is a drug within the meaning of Section 201(g). It is a new animal drug within the meaning of Section 201(v) since it is not generally recognized as safe and effective for the uses for which it is recommended in the labeling.

The [redacted] brand of [redacted] you market is adulterated under Section 501(a)(5) of the Act, in that it is a new animal drug within the meaning of Section 201(v) and is unsafe within the meaning of Section 512(a) of the Act since no applications have been approved pursuant to Section 512(b) for this drug.

The introduction or delivery for introduction of an adulterated drug into interstate commerce is a violation of Section 301(a) of the Act.

The receipt in interstate commerce of an adulterated drug, and the delivery or proffered delivery for pay or otherwise is a violation of Section 301(c) of the Act

This is not intended to be an all-inclusive list of violations. It is your responsibility to ensure that requirements of the Act and regulations are being met. Failure to achieve prompt corrective action may result in enforcement action without further notice, including seizure and/or injunction.

Within fifteen (15) days of the receipt of this letter, notify our Las Vegas office in writing of the specific steps you have taken to correct these violations and preclude their recurrence. made. Please direct your reply to Luis Chavarria, Investigator, U.S. Food and Drug Administration, P.O. Box 16028, Las Vegas, Nevada 89101.

Sincerely yours,

Patricia Ziobro
District Director
San Francisco District